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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,047	04/15/2004	Steven Odrich	2755.025US1	7403

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
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Office Action Summary	Application No.	Applicant(s)	
	10/825,047	ODRICH, STEVEN	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11, 13 - 19, 21 - 44* is/are pending in the application.

4a) Of the above claim(s) *13, 14, 16, 18, 19, 23 - 28, 32, 35, 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 15, 17, 21, 22, 29 - 31, 33, 34, and 37 - 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed April 22, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application. Applicants request for an interview is acknowledged. Applicant is invited to contact the Examiner via telephone to set up an interview.

Claim Rejections - 35 USC § 112 – 1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 39 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. None of the prostaglandin derivatives other than latanoprost, travaprost and bimataprost meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient

written description to support the entire genus of prostaglandin derivatives encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base prostaglandin molecule may be changed while remaining a derivative.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 – 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It unclear what is meant by the limitation "the active agent delivered on a sustained release basis to tissue at or near one or both of a first location proximal to an eye or a second location distal to the eye". "Distal" and "proximal" in this context refer to anatomical locations and as such are not interchangeable with "proximity" and "distance". Proximal means situated nearest to the point of origin or closest to the center of the body while distal refers to situated farthest from the point of origin or directed away from the midline of the body. Based on these anatomical definitions, the locations to which the active agent is intended to be administered cannot be determined.

5. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what materials fall within the limitation of "substantially inert". Very few materials are completely inert and do not react with anything else. It could be that Applicant means that the material is inert in that it does not react with the active agent(s) and/or that the material does not provoke a response upon insertion into a patient. It is also unclear how much reactivity would or would not be acceptable in whatever context because of the use of the word “substantially”. This indicates that the material need not be completely inert but can have some reactivity. Please clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (US 3,949,750). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 22, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that not all elements of the instant claims are taught by Freeman. Claim 11 recites an active agent dispersed "entirely throughout" the porous or absorbent material included in the implant body. Claim 30 recites an implant body including a porous or absorbent material incorporating an active agent from a proximal end portion to a distal end portion.

These arguments are not found persuasive. In regards to the new limitations regarding delivery to either a proximal and/or distal location from the eye, this limitation is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The plug of both the instant claims and Freeman releases the active ingredient into the lacrimal fluid so this limitation is met. The implant may be made of polytetrafluoroethylene (TEFLON®) or hydroxyethylmethacrylate hydrophilic polymers (col 4, ln 27 – 30), which are materials that are substantially inert.

It is not explicitly clear to the Examiner what elements Applicant is arguing are not taught by Freeman but it appears that Applicant is arguing is/are not taught by Freeman but it has been assumed that those elements are the portion of the claims presented in the text of the arguments. All but claim 34 do not require the entire body to be made of a porous or absorbent material as the implant body includes such a portion. Thus, portions of the implant body can be made of non-porous and non-absorbent materials. In regards to claim 34, Freeman discloses that that the plug, or the head

portion, can be made of medication-impregnable porous materials (col 5, ln 8 – 11), indicating that the entirety of the implant body can be made from such a material. Thus these limitations from the rejected claims are disclosed by Freeman.

8. Claims 11, 15, 17, 21, 22, 29 – 31, 33 and 37 – 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 22, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that not all elements of the instant claims are taught by Cohan et al. The insert body of Cohan is molded or otherwise formed from a material that is impermeable to the medication which will fill the reservoir and the operability relies on this fact so that the medication is directed out the collarette pore at the insert's proximal end. Claim 11 requires that the active agent be disposed entirely throughout the porous or absorbent material included in the implant body, not the reservoir within an interior surface of an insert body. Claim 24 requires that an exterior surface portion of the implant body release the active agent. Claim 30 requires an implant body including a porous or absorbent material incorporating an active agent from a proximal end portion to a distal end portion.

These arguments are not found to be persuasive. In regards to new claims, the silicone is taught as a material from which the implant can be formed (col 4, ln 28 – 31), which reads on a substantially inert material for the implant body. The anti-glaucoma drug and prostaglandin derivative latanoprost is an immediate candidate for

administration via the device (col 7, ln 5 – 10). In regards to the new limitations regarding delivery to either a proximal and/or distal location from the eye, this limitation is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The plug of both the instant claims and Cohan et al. releases the active ingredient into the lacrimal fluid so this limitation is met.

Claim 24 is withdrawn from consideration and is not currently being examined. The instant claims do not require the entire body to be made of a porous or absorbent material as the implant body includes such a portion. Thus, portions of the implant body can be made of non-porous and non-absorbent materials. Those portions of the implant body made of the porous or absorbent material must have the active agent disposed entirely throughout, but the entire implant need not be disposed throughout the entire body of the implant body. Therefore all of the limitations of the instant claims are disclosed by Cohan et al. and this rejection is MAINTAINED.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 11, 15, 17, 21, 22, 29 – 32, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Bhushan (US 2004/0137068). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 22, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that there is motivation to combine when the references teaches away from the claimed combination. Bhushan

teaches away from the claimed body implant by teaching a medication reservoir within an interior surface of an insert body. This combination is therefore improper and fails to establish all the recited elements.

These arguments are not found persuasive. As discussed in greater detail above, Freeman does teach an implant body including a porous or absorbent material wherein the active agent is disposed entirely throughout. The teaching, suggestion or motivation is not the only reasoning by which a prima facie case of obviousness can be properly constructed (see MPEP 2141 - 2144). While Bhushan discloses an internal reservoir and an outer membrane, that does not teach away from the length of time over which the medication contained within the punctual plug device should be release. Both Freeman and Bhushan use diffusion of the active agent from the implant to release the medication, and Bhushan teaches that for the delivery of medication to the eye is a long term endeavor that must be continued for prolonged periods of time (¶ [0082]). The combination of the two references is proper as one of ordinary skill in the art would use the teachings of Bhushan to determine an optimal dosing length for the ocular drug delivery devices, Regardless of the different physical arrangement by which the sustained release of the active agent is achieved.

13. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Cohan et al. (US 6,196,993).

Freeman discloses a punctal plug by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region (part 28 or 28') and a lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), or particularly the head portion, can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). Thus, Freeman discloses a punctual plug in which the head or body has a medication-discharge from an exterior surface portion of the plug body and provides a sustained release of the active ingredient from the plug. The portion of the implant body comprised of porous or absorbent material has the active agent disposed entirely throughout that portion.

Freeman does not explicitly disclose a prostaglandin derivative such as latanoprost as an active agent suitable for delivery by the punctual plug,

Cohan et al. discloses that latanoprost is an anti-glaucoma drug that can be delivered by means of punctual plug device which releases the active agent onto the eye (col 7, ln 4 – 10; abstract)

It would have been obvious to one ordinary skill in the art at the time of the instant to prepare a punctal plug as taught by Freeman and to use latanoprost as the active ingredient. The person of ordinary skill in the art would have been motivated to

make those modifications and reasonably would have expected success because Cohan et al. teaches that latanoprost is an anti-glaucoma agent suitable for direct administration to the eye.

14. Claims 11, 15, 17, 21, 22, 29 – 31, 33 and 37 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohan et al. (US 6,196,993) in view of Bhushan (US 2004/0137068). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 22, 2008 and those set forth below.

Applicant has not specifically addressed this rejection, so the rejection is maintained for the reasons set forth above with regard to Cohan et al. alone above and those set forth in the October 22, 2008 Office action regarding Cohan et al. and Bhushan.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW